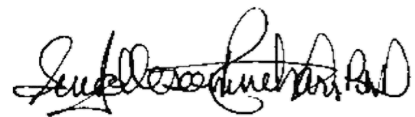


Bleach vs Bubbles: Assessment of the Effect of Bathroom Environment on Pediatric Atopic Dermatitis

By: Kelly Jo Tackett

A Master's Paper submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Public Health in the Population Health for Clinicians Program

Chapel Hill
Summer Semester 2020



Sue Tolleson-Rinehart, PhD

3 July 2020

Date



Craig Nathaniel Burkhardt, MD MPH MS

7/3/2020

Date

© 2020
Kelly Jo Tackett
ALL RIGHTS RESERVED

ABSTRACT

Kelly Jo Tackett: Bleach vs Bubbles: Assessment of the Bathroom Environment on Pediatric Atopic Dermatitis
(Under the direction of Dr. Sue Tolleson Rhinehart PhD, and Dr. Craig Burkhardt MD, MPH, MS)

Dilute bleach (sodium hypochlorite, NaOCl) baths are commonly recommended in clinical practice guidelines for pediatric eczema, also known as atopic dermatitis (AD) management.¹ Although the original randomized control trials (RCT) of bleach baths were promising, subsequent RCTs have shown conflicting results.² Currently, no studies investigate the role of improving environmental hygiene in reducing the severity of atopic dermatitis. This paper seeks to explore the efficacy of bleach baths in the context of improvement of the bathroom hygiene environment on severity of pediatric atopic dermatitis.

At the start of the study, two-thirds of the participating patients were randomized to have a culture taken from their bathtub, followed by cleaning of all of their bathrooms (intervention arm); the remaining one-third of the sample only had a culture taken from their bathtub, with no cleaning (control arm). After investigators cleaned the bathrooms in the intervention arm, this group was randomized again, with half receiving instructions on performing twice weekly bleach baths and the other half not receiving these instructions. Study outcomes included POEM (patient-oriented eczema measurement) scoring at time of home visit, 1 week after visit, and 4 weeks after visit, as well as bathtub culture results and rates of infection. This study design was modestly altered: restrictions on field research caused by the COVID-19 global pandemic

resulted in our having a final sample of 58 patients, rather than the 60 for which we had hoped.

This study revealed no significant difference in POEM score between the patients who received a bathroom cleaning and those who were in the bleach bath group. The control group showed a statistically significantly higher POEM score, indicating higher morbidity caused by their atopic dermatitis than was experienced in the bleach bath or cleaning group.

This study suggests that the efficacy of bleach baths in AD may be the result of hygienic bathroom environments rather than directly exposing children to a bleach bath.

ACKNOWLEDGEMENTS

I would like to offer a special thank you to those who have assisted me in this project for my Master's Paper.

Dr. Burkhart: Thank you for your continued mentorship and support throughout my education. You are the only person who could talk me into cleaning bathrooms. I appreciate you so much!

Dr. Tolleson-Rinehart: Thank you for being such a wonderful advisor throughout the MPH program. I value your insight and guidance more than you know!

Dr. Morrell and Dr. McShane: Thank you for allowing me to recruit patients from your clinic and always supporting my never-ending projects!

Dr. Smedberg and Dr. Johnson: Thank you so much for your assistance with plating and growing our micro samples.

Dr. Tan: Thank you for helping me with understanding statistics!

To the patients: Thank you for trusting me and inviting me into your homes. I will be forever humbled and grateful for what you have taught me.

TABLE OF CONTENTS:

Abstract.....	i
Acknowledgements.....	iii
Table of Contents	iv
Introduction.....	1
Background and Significance.....	2
Methods.....	4
Results.....	7
Discussion.....	10
Conclusion.....	13
References.....	15
Figures.....	17
Tables.....	20
Appendix 1.....	27
Appendix 2.....	34

INTRODUCTION:

Atopic dermatitis (AD) is the most common skin disease in childhood and is the leading cause of pediatric dermatology visits in developed nations (Silverberg et al., 2017). AD is a chronic, inflammatory skin disease characterized by pruritis, inflammatory erythematous skin lesions, and skin-barrier defect (Nguyen et al., 2019). Current AD treatments include use of emollients, steroids, calcineurin inhibitors, and systemic immunomodulators (Silverberg et al., 2017). Dilute bleach (sodium hypochlorite, NaOCl) baths are commonly recommended in clinical practice guidelines for pediatric eczema, also known as atopic dermatitis (AD) management (Eichenfield, 2004, Weitz et al., 2006). Bleach baths are proposed to suppress epidermal *Staphylococcus Aureus* load, which subsequently improves atopic dermatitis severity (Guzik et al., 2015). Although the original randomized control trials (RCT) of bleach baths were promising, subsequent RCTs have shown conflicting results (Chopra et al., 2017). Additional evidence from a Cochrane review indicates that reducing the load of *Staphylococcus Aureus* in patients with atopic dermatitis does not provide clinical benefit in the absence of active infection (Bath-Hextall, 2010).

Currently, no studies investigate the role of improving environmental hygiene in reducing the severity of atopic dermatitis. This question is controversial, as the current “hygiene hypothesis” postulates that exposure to “dirtier environments” in which children are exposed to more bacterial and viral pathogens is protective against atopic dermatitis (Flohr & Yeo, 2011). This paper seeks to explore the efficacy of bleach baths in the context of improvement of the bathroom hygiene environment on severity of pediatric atopic dermatitis.

BACKGROUND AND SIGNIFICANCE

Environmental Hygiene and Atopic Dermatitis

The “atopic triad” of disease includes asthma, atopic dermatitis, and allergies; they are commonly inherited together and are a result of hypersensitivity to certain stimuli (Kapoor et al., 2008). The relationship between environmental interventions and disease severity is much better understood in conditions like asthma than for atopic dermatitis. In asthma, home-based multi-trigger, multicomponent interventions with an environmental focus for children and adolescents with asthma show strong evidence for improving asthma symptoms, reducing the number of days of school missed due to asthma, and improve overall quality of life (Crocker et al., 2011). In contrast, studies looking at environmental hygiene interventions for atopic dermatitis are formulated to search for hygiene improvements as the *cause* of atopic dermatitis, rather than factor of improvement. One atopic dermatitis study evaluated the effect of more frequent hand washing and the use of antiseptics in daycare centers on the development of allergies later in life and found that more hygienic daycares do not increase the risk for allergies (Dunder et al., 2007). Another study found that children who live in families who wash themselves more frequently have a higher risk for atopic dermatitis, however, the authors only assessed skin washing (not environmental hygiene), and their finding was likely of irritation of the skin barrier caused by increased soap use, rather than a reduction in pathogen exposure (Sherriff & Golding, 2002; Flohr & Yeo, 2011). Additionally, these studies did not assess the relationship between increasing environmental hygiene and atopic dermatitis symptoms in children who already had the

disease. Finally, the gut microbiome of children with atopic dermatitis is more often colonized with *Staphylococcus aureus* and coliform microbes, with these changes often preceding clinical manifestations of atopic dermatitis (Bjorksten et al., 1999; Bjorksten et al., 2001; Wantanabe et al., 2003). Currently, the relationship between environmental hygiene and atopic dermatitis severity has not been explored in relation to the gut microbiome. If atopic dermatitis behaves similarly to asthma, it is plausible that an intervention that reduces mold and bacteria in the bathroom environment could improve atopic dermatitis severity.

Environmental Hygiene Methods

The Centers for Disease Control and Prevention (CDC) publishes guidelines on safely cleaning homes by homecare workers (CDC, 2015 and CDC, 2018). Tubs, tiles, showers, and toilets are recommended to be cleansed with baking soda mixed with warm water. Floors can be cleansed with white vinegar diluted in water. Hard surfaces, including floors, sinks, certain toys, and countertops with evidence of mold growth can be cleansed with dilute bleach. The cleaning intervention used in this project included only these cleansing agents (water, dish soap, white vinegar, baking soda, and bleach when indicated) as they are relatively inexpensive and widely available agents that could be generalized to diverse populations if the intervention is proven to be clinically effective.

The role of the bathroom environment in atopic dermatitis and allergy is unknown. This study evaluates whether part of the efficacy of bleach baths in atopic dermatitis may be from improving the hygiene of the bathroom environment by

presumably reducing the amounts of bacteria and mold located in the bathtub. If shown to be clinically effective at reducing both the number of infections and the disease severity of atopic dermatitis, improved bathroom hygiene may change the current clinical practice guidelines of recommendations for dilute bleach baths in children with eczema. Additionally, the use of inexpensive and widely available agents to clean bathrooms (water, dish soap, white vinegar, bleach, and baking soda) would be generalizable to diverse populations.

METHODS

I recruited willing patients and their families by in-person invitations from Pediatric Dermatology clinics at The University of North Carolina at Chapel Hill from August 2019- February 2020. I intended to recruit 60 families to participate and powered the study for that N of cases. At the start of the study, two-thirds of the patients (40 patients) were randomized to have a culture taken from their bathtub, with subsequent cleaning of all of their bathrooms by the lead investigator (intervention arm), with one-third (20 patients) only having a culture taken from their bathtub with no cleaning (control arm). After I, the lead investigator, cleansed the bathrooms most often used by the children with AD in the intervention arm, I randomized this group again, such that half of this group (20 patients) receives instructions on performing twice weekly bleach baths and the other half (20 patients) does not (see Appendix). The COVID-19 global pandemic suspended all field research at UNC in early Spring 2020. Fortunately, I had already enrolled 58 patient families, and had already conducted the intervention. As a

result, the study to date includes 20 patients in the cleaned bathroom plus bleach bath arm, 19 patients in the cleaned bathroom arm, and 19 in the control arm.

This project included four quantitative assessment phases. Upon entry into the study, I collected basic demographic information (race/ethnicity, age, insurance status), a history of skin infections and allergic diseases, an atopic dermatitis severity score (POEM or Patient Oriented Eczema Measure), an atopic dermatitis area and severity score (EASI score, or eczema assessment and severity index), and recorded level of AD therapy (weak-moderate topical steroids, strong topical steroids, or systemic immunomodulators). I obtained cultures from the bathtub used by every child with AD recruited into the study. I obtained a POEM score on the date of scheduled swab or cleaning, followed by getting a one-week follow up POEM score over the phone, as well as a 4-week POEM score. Additionally, I kept detailed field notes of my own perceptions and experiences using a structured note-taking tool for every home visit during the cleaning process (Appendix Item4). Domains assessed in the field notes include environment, work difficulty, and assessment of usefulness to the family. Environmental notes included the general appearance of the exterior of the home and neighborhood, cleanliness and order within the home and bathroom, the hospitality and dynamics of family interactions. Work difficulty notes included description of activities performed and any physical, mental, and emotional toil related to the labor with suggestions for improving the work experience. Assessment of usefulness to the family included patient and family perception of intervention, willingness to complete dilute bleach baths, and intention to use educational information about bathroom cleanings. My findings from the

home visit field notes were coded by a single investigator, me; I evaluated the results for recurring themes.

I randomized participating families into one of three interventions using the RANDBETWEEN function in Excel. While it was not possible to blind participants to which intervention they were randomized to, the POEM scores were obtained by a blinded investigator. I contacted participants via phone with the results of their bacteria culture at 4 weeks following the home visit, and I gave all participants instructions on cleaning the bathroom at the 4-week mark, regardless of intervention arm.

Study inclusion criteria were children with atopic dermatitis between 6 months and 18 years of age who visited UNC Pediatric Dermatology during the study enrollment period who were on a class 1 topical steroid or systemic immunosuppressive agent to control his or her eczema at the time of recruitment. Additionally, I required that potential participants had a history or current clinical evaluation by a Board-Certified Pediatric Dermatologist showing atopic dermatitis affecting at least 10% of total body surface area to participate in this study. Exclusion criteria included the patient or family member with a sensitivity to bleach, a child that has used bleach baths within the last two months, or children who took showers instead of baths.

I performed statistical analysis in Microsoft Excel. Wilcoxon ranked sum test was used to test for normal distribution among each group, with p value <0.05 being considered a statistically significant difference. Fisher's combined probability test and chi squared test were used to detect differences in POEM scores, EASI scores, and post-intervention survey results, with p value <0.05 being considered a statistically significant result.

RESULTS

Study Sample Characteristics

As I noted above, this study was originally intended to be statistically powered for 60 patients, however the restrictions imposed in response to the COVID-19 global pandemic interrupted data collection near the end of the recruitment period. As a result, there were 20 patients in the bleach bath arm, 19 patients in the bathroom cleaning arm, and 19 in the control arm, for a total of 58 patients. This study sample was mainly represented by children who identified as black, white, or Asian (see Table 1). The average age of study participants was 7.35 years, and locations of homes were distributed throughout the state of North Carolina, primarily concentrated in the central area of the state (see Figure 3). Self-reported race of participants was black (48.3%), white (31.7%), Asian (5%), multiracial (10%), and other (3.3%) (see Table 1). Study participants also self-reported insurance coverage of Medicaid (55%), Blue Cross Blue Shield (16.7%), Tricare, or health insurance for the families of active duty military personnel (10%), and others (18.3%) (see Table 1). I obtained background medical history of atopic disease, skin infections, current antibiotic use, and type of treatment for AD upon families' enrollment in the study. Atopic disease history of participants included previous diagnosis of asthma (40%), history of hay fever (71.7%), and history of food allergies (40%) (see Table 2). Infection history of participants included prior history of skin infections requiring treatment with antibiotics (51.7%), current topical antibiotic use (6.7%), and current systemic antibiotic use (8.3%) (see Table 2). Participant AD treatment regimens included topical class 1 corticosteroids (65%) and systemic

immunomodulator (31.7%) and other (3.3%) (see Table 2). Baseline assessment of AD severity was a combination of treatment regimen, EASI score, and POEM score (see Appendix 2). Average EASI score at time of study enrollment was 11.84 (see Table 3) and average POEM was 13.88 (see Table 4). Six participants did not complete the full study, because they were moving homes, or parents could not be home at the time of home visit, or they did not answer during attempts to contact for follow up surveys.

Analysis of Home Visit Themes Emerging from Field Notes

I concluded each home visit with an interview and a write up of my own experiences with cleaning, patient and family education, and relevant notes on living environment (see Appendix 2, Item 4). These notes show that participants with higher baseline EASI and POEM scores were more likely to live in rented homes, have noticeable odor of smoke within the home, live in crowded homes with shared bathrooms, use fragrances or air fresheners within the home, have carpet throughout the home, and excessive mold within the bathtub (see Figure 1). Participants with lower baseline EASI and POEM scores were more likely to live in homes with tile or wood floors, to own their homes, to have minimal mold in the bathtub, use home cleaning services, and were more likely not to have noticeable odors of smoke, air fresheners, or fragrance (see Figure 1).

Bathtub Culture Results

I swabbed bathtubs at the start of each home visit and sent them to UNC Microbiology Labs to determine flora present in the tub prior to cleaning. The most commonly isolated bacterium was *Staphylococcus aureus* (12), followed by KEE organisms (grouped *Klebsiella*, *Enterobacter*, *Escherichia coli*) (7), and Methicillin Resistant *Staphylococcus aureus* (2) (see Figure 1 and Table 5). The majority of bathtubs were found not to have *S. aureus*, KEE, or MRSA (31). In a small number of cases, I could not obtain samples from bathtubs because of dropouts or missing lab samples (6). There was no statistically significant difference in isolated flora between the bleach bath group, cleaning group, and control group (*Fisher p* = 0.9874). Families who were not randomized into the cleaning group who were found to have potentially pathogenic bacteria were contacted and given instructions on disinfecting their bathtubs (see Appendix 2 Item 3).

Post Intervention Results

I contacted participants at one week and 4 weeks following initiation of their respective interventions. No statistically significant difference was detected between baseline and post-intervention POEM scores in the bleach bath group and the bathroom cleaning group (Wilcoxon $p = 0.1458$) (see Table 6). The average change in 4-week POEM score for the bleach bath group was 1.94. The average change in 4-week POEM score for the bathroom cleaning group was 4. The average change in the 4-week POEM score for the control group was 0.53 (see Table 6). Participants were asked to

self-report on skin infections experienced within the last 4 weeks. The bleach bath group and cleaning group combined had a 2.5% infection rate while the control group had a 5% (see Table 7). The bleach bath group and cleaning group also had a 12.5% use of systemic antibiotics within the 4-weeks following the intervention, while the control group had 15% (see table 7).

Additionally, 10% of participants in the bleach bath and cleaning intervention groups report use of systemic steroids, while the control group reported a rate of 15% use (see Table 7). The bleach bath group and cleaning group also reported that 5.1% of participants required a visit to their medical provider for an AD flare within the four weeks following the intervention, while the control group reported twice as many, or 10%, that they needed to see their providers (see Table 7). Six participants did not complete the full study, because they were moving homes, or parents could not be home at the time of home visit, or they did not answer during attempts to contact for follow up surveys. Four of these patients were Medicaid patients, with the most common reason of these dropouts being inability to reach participants over the phone.

DISCUSSION

This convenience sample of 58 children from 36 counties demonstrates strong associations between the bathroom environment and severity of pediatric AD. This study suggests that the efficacy in bleach baths for AD treatment may not be exclusively beneficial via decolonization of skin, but also by contributing to improvement in hygiene of the bathroom environment. These findings are consistent with prior literature about the relationship of asthma, which indicated environmental triggers are a contributor to

increasing disease severity (Dunder et al., 2007). However, this study may call for reconsideration of the previous hygiene hypothesis, which postulated that “dirtier environments” in which children are exposed to more bacterial and viral pathogens, are protective against atopic dermatitis (Flohr & Yeo, 2011). Both the bleach bath group and bathroom cleaning group had improved POEM scores, while the control group did not. The two intervention groups also had lower infection rates, medical visits for AD flairs, steroid use, and antibiotic use (see Table 7). The failure of differences between the bleach bath group and the bathroom cleaning group for these outcome measures may be a result of the small subsample sizes, indicating a strong need for future research, in larger numbers of participating families, to differentiate the effects of having bleach water on the skin and having a disinfected bathtub.

As is the case in so many other disease states, the effects of social determinants of health are moving to the forefront in consideration of disease severity for AD (Tackett et al., 2019). Social determinants of health have been defined as “the conditions in which people are born, grow, live, work, and age, which are in turn shaped by the distribution of power, money, and resources within and between countries” (Baker et al., 2018). Variables like socioeconomic status, environment, and poor disease outcomes have been linked by the theory of fundamental causes (Link et al., 1995). This theory provides a framework for understanding why health inequities continue to exist despite medical advances and efforts to eliminate them at the individual and health systems level. The theory of fundamental causes prioritizes the availability of resources to persons with higher socioeconomic status, such as knowledge, power, money, and beneficial social connections that operate at individual and community levels and that

can be used despite any risk or protective factors to improve health (Phelan et al., 2010). This theory may enrich our understanding of the results from the findings and themes I collected during home visits, including meeting and witnessing participants with lower socioeconomic status, less hygienic bathroom environments, and living in potentially lower-resource neighborhoods having higher measures of AD severity, including higher EASI and POEM scores (see Figure 3). These findings comport with studies and national data for numerous other disease states, underlining the importance of affordable housing, clean environments, jobs that pay a living wage, and access to clinical care and healthy foods (Acevedo-Garcia et al., 2003). Despite this data, few countries have systematically approached these health inequities.

Participants in this study spanned a wide range of socioeconomic status, geographic location, home environment, and family structure. Despite these differences, the theme of socially and economically disadvantaged children having higher AD disease severity prevailed in the findings. Many of these disadvantaged families drove over an hour to see a pediatric dermatology specialist who would accept Medicaid patients. These families commonly lived in cluttered and overcrowded homes, had excessive mold present in bathrooms, and had indoor environments including heavy smoke or fragrances (see Figure 3). The fact that there were families within this study who could not afford heat in the winter or who had to funnel running water from their sink into their bathtub yet prioritized driving their child two hours to seek health care for their severe AD highlights the necessity for policy change within the American health care system. Possible reform actions include the creation of culturally competent health care systems, insurance reform to compensate private practice specialist physicians for

providing care to low income patients, and societal improvements including job creation, economic stability, transportation access, food access, environmental sustainability, and educational attainment (Rudolph et al., 2013).

Study Limitations

Limitations in this study's sampling and methodology should be addressed. First, patients were recruited from one academic referral center in North Carolina, thus, it is possible that the results may not be generalizable to the State and National levels. Second, a non-random convenience sample from a pediatric specialty clinic was recruited to participate in this study, thus selection bias may have affected the results. Third, despite blinding the follow up investigator, blinding among participants was not possible, given the nature of the intervention. Fourth, I had no measures of compliance in the bleach bath group following the initial intervention. Finally, I collected follow up data via telephone, thus collecting an EASI score at the close of the study was not possible. Despite inevitable limitations in a study of this size, these results give reason to further research and understand the efficacy of bleach baths and the relationship between environmental hygiene and atopic disease.

CONCLUSIONS

This study highlights the role of environmental triggers, specifically bathroom hygiene, and its relationship to atopic dermatitis. Current practice guidelines for pediatric atopic dermatitis include the recommendation of dilute bleach baths for improvement in symptom management as well as reduction of skin infections. Previously, the mechanism for this improvement had been attributed to suppression of

the epidermal *Staphylococcus aureus* load (Guzik et al., 2005). This study shows that the benefit of bleach baths may not be exclusively derived from soaking in bleach water, but from improvement to the hygiene of the bathroom environment.

|

REFERENCES

1. Acevedo-Garcia D, L. K. (2003). Future directions in residential segregation and health research: a multilevel approach. *American Journal of Public Health*, 93, 215-221.
2. Baker P, Friel S, Kay A, Baum F, Strazdins L, Mackean T. What enables and constrains the inclusion of the social determinants of health inequities in government policy agendas? A narrative review. *Int. J. Health Policy Manag.* 2018;7(2):101-111. doi:10.15171/ijhpm.2017.130.
3. Bath-Hextall FJ, Birnie AJ, Ravenscroft JC, et al. Interventions to reduce *Staphylococcus aureus* in the management of atopic eczema: an updated Cochrane review. *Br J Dermatol.* 2010;163:12e26.
4. CDC. Practical Tips for Homecare Workers. 2015. Accessed at: https://www.cdc.gov/niosh/docs/2015-102/pdfs/f14_handout_3_2015-102.pdf
5. CDC. Household Cleaning & Sanitizing. 2018. Accessed at: <https://www.cdc.gov/healthywater/emergency/cleaning-sanitizing/household-cleaning-sanitizing.html>
6. Charman CR, Venn AJ, Ravenscroft JC, Williams HC. Translating Patient-Oriented Eczema Measure (POEM) scores into clinical practice by suggesting severity strata derived using anchor-based methods. *Br. J. Dermatol.* 2013;169(6):1326-1332. doi:10.1111/bjd.12590.
7. Charman CR, Venn AJ, Williams HC. The patient-oriented eczema measure: development and initial validation of a new tool for measuring atopic eczema severity from the patients' perspective. *Arch. Dermatol.* 2004;140(12):1513-1519. doi:10.1001/archderm.140.12.1513.
8. Chopra R, Vikharia PP, Sacotte R, et al. Efficacy of bleach baths in reducing severity of atopic dermatitis: A systematic review and meta-analysis. *Ann Allergy Asthma Immune.* 2017;119:435-440.
9. Clayton TH, Clark SM, Britton J, Pavlov S, Radev S. A comparative study of the Children's Dermatology Life Quality Index (CDLQI) in paediatric dermatology clinics in the UK and Bulgaria. *J. Eur. Acad. Dermatol. Venereol.* 2007;21(10):1436-1437. doi:10.1111/j.1468-3083.2007.02249.x.
10. Dunder T, Tapiainen T, Pokka T, Uhari M: Infections in child day care centers and later development of asthma, allergic rhinitis, and atopic dermatitis: prospective follow-up survey 12 years after controlled randomized hygiene intervention. *Arch Pediatr Adolesc Med* 2007;161:972–977.
11. Eichenfield LF. Consensus guidelines in diagnosis and treatment of atopic dermatitis. *Allergy.* 2004;59(suppl 78):86e92.
12. Flohr C and Yeo L. Atopic Dermatitis and the Hygiene Hypothesis Revisited. *Curr Probl Dermatol.* Basel, Karger. 2011;41:1-34.
13. Guzik TJ, Bzowska M, Kasproicz A, et al. Persistent skin colonization with *Staphylococcus aureus* in atopic dermatitis: relationship to clinical and immunological parameters. *Clin Exp Allergy.* 2005;35:448e455.
14. Kapoor R, Menon C, Hoffstad O, Bilker W, Leclerc P, Margolis DJ. The prevalence of atopic triad in children with physician-confirmed atopic dermatitis. *J. Am. Acad. Dermatol.* 2008;58(1):68-73. doi:10.1016/j.jaad.2007.06.041.

15. Link BG, P. J. (1995). Social Conditions as Fundamental Causes of Disease. *Journal of Health and Social Behavior*, 35(extra issue), 80-94.
16. Nguyen HL, Anderson KR, Tollefson MM. New and emerging therapies for pediatric atopic dermatitis. *Paediatr Drugs* 2019;21(4):239-260. doi:10.1007/s40272-019-00342-w.
17. Phelan JC, L. B. (2010). Social Conditions as Fundamental Causes of Health Inequalities: Theory, Evidence, and Policy Implications. *Journal of Health and Social Behavior*, 5(S), S28-S40.
18. Rudolph L, C. J.-M. (2013). *Health in All Policies: A Guide for State and Local Governments*. Washington, DC and Oakland, CA: American Public Health Association and Public Health Institute.
19. Silverberg NB, Durán-McKinster C. Special considerations for therapy of pediatric atopic dermatitis. *Dermatol. Clin.* 2017;35(3):351-363. doi:10.1016/j.det.2017.02.008.
20. Sherriff A, Golding J: Hygiene levels in a contemporary population cohort are associated with wheezing and atopic eczema in preschool infants. *Arch Dis Child* 2002;87:26-29.
21. Tackett KJ, Jenkins F, Morrell DS, McShane DB, Burkhart CN. Structural racism and its influence on the severity of atopic dermatitis in African American children. *Pediatr. Dermatol.* 2019. doi:10.1111/pde.14058.
22. Watanabe S, Narisawa Y, Arase S, Okamatsu H, Ikenaga T, Tajiri Y, Kumemura M: Differences in fecal microflora between patients with atopic dermatitis and healthy control subjects. *J Allergy Clin Immunol* 2003;111:587–591.
23. Weitz NA, Brody E, Lauren CT, et al. Management of infectious aspects of atopic dermatitis in primary care: a resident survey. *Clin Pediatr (Phila)*. 2016; 55:1295e1299.

FIGURES:

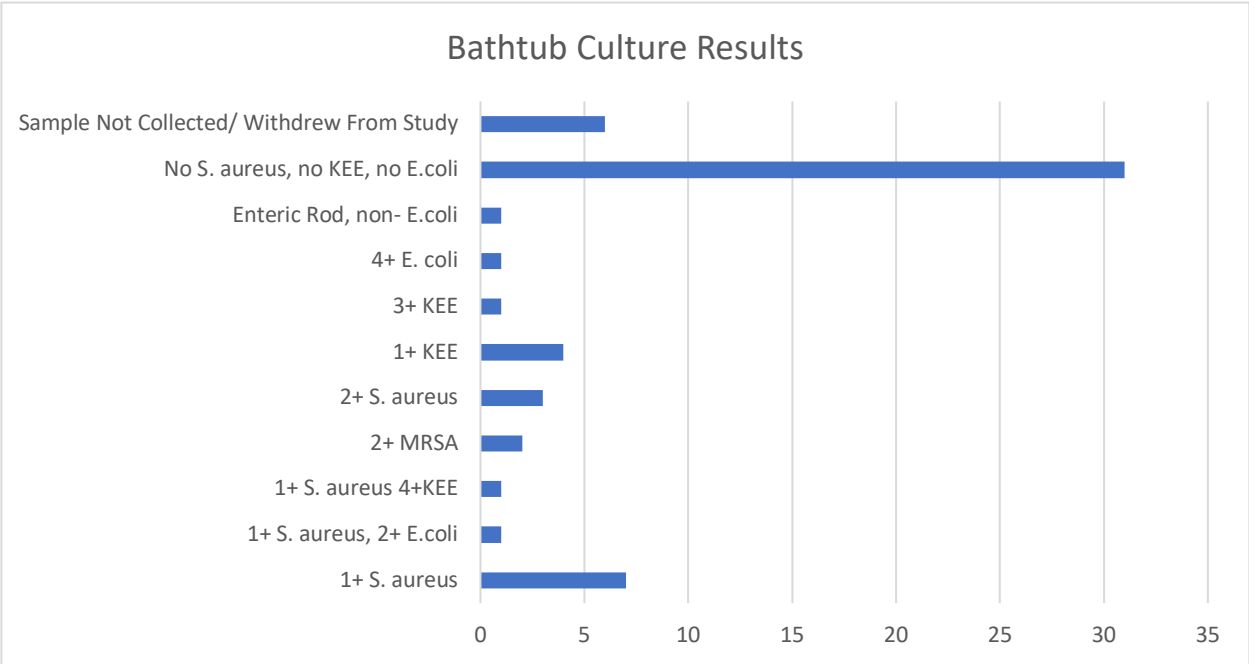


Figure 1: Bathtub Culture Results, Fisher p = (0.9874)

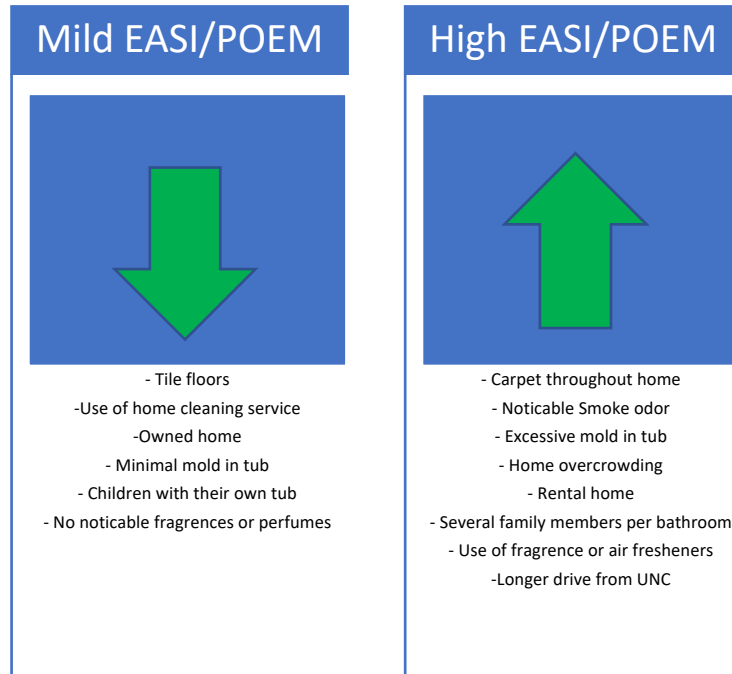
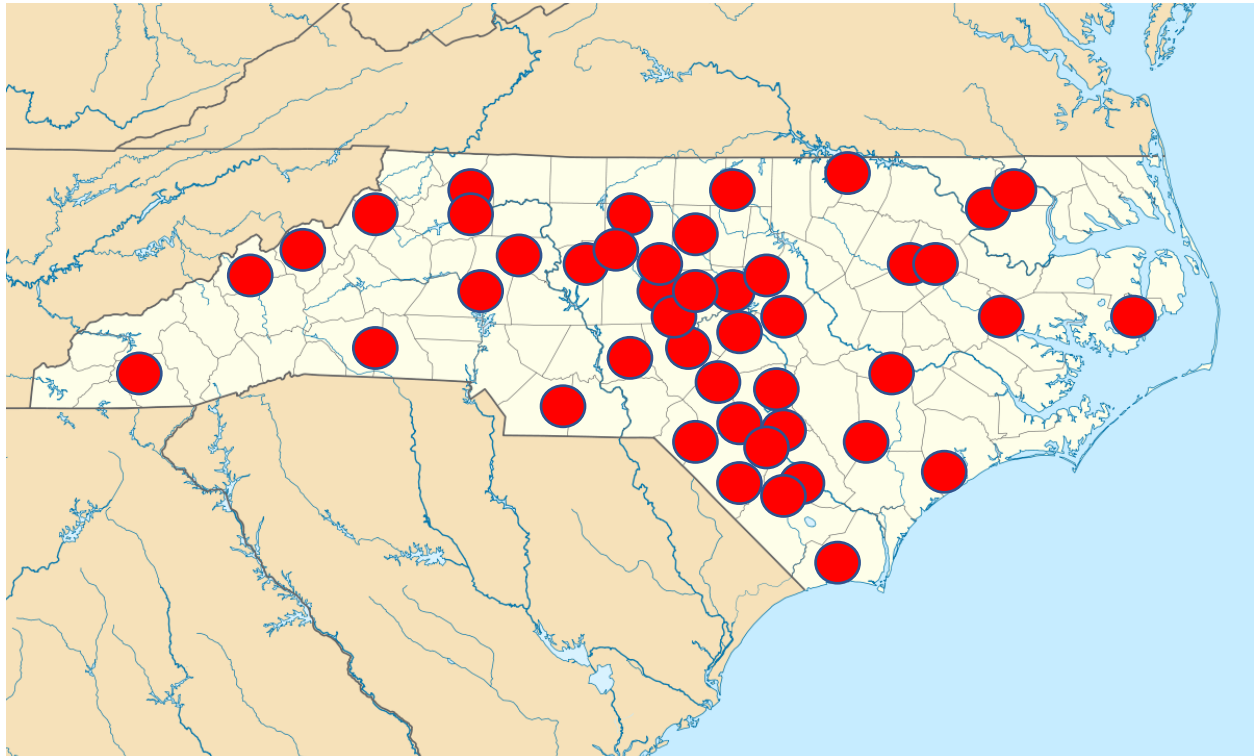


Figure 2: Recurring Themes from Qualitative Assessment Compared to Intake EASI/POEM Scores



*Figure 3: Geographic Distribution of Home Visits**

*Note: to protect patient privacy, dots have been shifted slightly and may represent one or more patients from sample population

TABLES:

Table 1: Patient Demographic Information

	Bleach Group + Cleaning Group (Arm 1 & 2)	Control (Arm 3)	Total/ p values
Average age (years)	7.35	6.87	7.19 <i>Wilcoxon p = (0.601)</i>
Race (self-reported)	-	-	<i>Fisher p = (0.5546)</i>
Black	22 (55%)	7 (35%)	29 (48.3%)
White	10 (25%)	9 (45%)	19 (31.7%)
Asian	2 (5%)	1 (5%)	3 (5%)
Multiracial	4 (10%)	2 (10%)	6 (10%)
Other	1 (2.5%)	1 (5%)	2 (3.3%)
Ethnicity (self-reported)	-	-	<i>Fisher p = (1)</i>
Hispanic or Latino	1 (5%)	1 (5%)	2 (5%)
Non-Hispanic or Latino	37 (95%)	19 (95%)	56 (95%)
Insurer	-	-	<i>Fisher p = (0.3026)</i>
Aetna	0 (0%)	1 (5%)	1 (1.7%)
BCBS	9 (22.5%)	1 (5%)	10 (16.7%)
Cigna	1 (2.5%)	1 (5%)	2 (3.3%)
Medicaid	22 (55%)	11 (55%)	33 (55%)
NC Health Choice	0 (0%)	1 (5%)	1 (1.7%)
Tricare	3 (7.5%)	3 (15%)	6 (10%)
UMR	1 (2.5%)	0 (0%)	1 (1.7%)
United	3 (7.5%)	1 (5%)	4 (6.7%)
No Insurer Reported	1 (2.5%)	1 (5%)	2 (3.3%)

SOURCE: “Bleach vs. Bubbles” Study, data gathered by author, 2020.

Table 2: Patient Medical History

	Bleach Bath Group & Bathroom Cleaning Group	Control Group	Total/ p values
History of Diagnosed Asthma?	-	-	<i>Fisher p = (1)</i>
No	23 (57.5%)	11 (55%)	34 (56.7%)
Yes	16 (40%)	8 (40%)	24 (40%)
No Data	1 (2.5%)	1 (5%)	2 (3.3%)
History of Hay Fever?	-	-	<i>Fisher p = (0.2995)</i>
No	8 (20%)	16 (80%)	15 (25%)
Yes	15 (37.5%)	3 (15%)	43 (71.7%)
No Data	1 (2.5%)	1 (5%)	2 (3.3%)
History of Food Allergies?	-	-	<i>Fisher p = (0.6236)</i>
No	24 (60%)	10 (50%)	34 (56.7%)
Yes	15 (37.5%)	9 (45%)	24 (40%)
No Data	1 (2.5%)	1 (5%)	2 (3.3%)
History of Skin Infection Requiring Antibiotics?	-	-	<i>Fisher p = (1)</i>
No	18 (45%)	17 (85%)	27 (45%)
Yes	21 (52.5%)	2 (10%)	31 (51.7%)
No Data	1 (2.5%)	1 (5%)	2 (3.3%)
Current Topical Antibiotic Use?	-	-	<i>Fisher p = (0.501)</i>
No	37 (92.5%)	17 (85%)	54 (90%)
Yes	2 (5%)	2 (10%)	4 (6.7%)
No Data	1 (2.5%)	1 (5%)	2 (3.3%)
Current Systemic Antibiotic Use?	-	-	<i>Fisher p = (1)</i>
No	35 (87.5%)	18 (90%)	53 (88.3%)
Yes	4 (10%)	1 (5%)	5 (8.3%)
No Data	1 (2.5%)	1 (5%)	2 (3.3%)
Current AD Therapy?	-	-	<i>Fisher p = (0.6056)</i>
Class 1 Topical Steroid	25 (62.5%)	14 (70%)	39 (65%)
Systemic Immunomodulator	14 (35%)	5 (25%)	19 (31.7%)
No Data	1 (2.5%)	1 (5%)	2 (3.3%)

SOURCE: "Bleach vs. Bubbles" Study, data gathered by author, 2020

Table 3: Baseline EASI Scores

Wilcoxon p = (0.8296)

	Bleach Baths & Bathroom Cleaning	Bathroom Cleaning Only	Control	Total
n	16	20	18	54
Mean	11.34	12.53	11.53	11.84
Std	9.81	9.45	7.26	8.74
Min	2.40	0.20	1.70	0.20
1st Qtr	4.27	5.90	5.55	5.35
Median	7.35	9.06	10.60	8.80
3rd Qtr	14.9	17.92	14.12	16.52
Max	39.6	33.60	25.8	39.6

SOURCE: “Bleach vs. Bubbles” Study, data gathered by author, 2020

Table 4: Baseline POEM Scores at Study Enrollment

	Bleach Baths & Bathroom Cleaning	Control	Total
n	39	19	58
Mean	14.31	13	13.88
Std	7.3	4.97	6.61
Min	2	4	2
1st Qtr	7.5	10	8.25
Median	14	12	13.5
3rd Qtr	20	15.5	18.75
Max	29	24	29

SOURCE: “Bleach vs. Bubbles” Study, data gathered by author, 2020

Table 5: Bathtub Culture Results

Fisher p= (0.9874)

	Bleach Baths & Bathroom Cleaning	Bathroom Cleaning Only	Control	Total
1+ S. aureus	2	4	1	7
1+ S. aureus, 2+ E. coli	1	0	0	1
1+ S. aureus, 4+ KEE	0	0	1	1
2+ MRSA	1	1	0	2
2+ S. aureus	1	1	1	3
1+ KEE	1	2	1	4
3+ KEE	0	0	1	1
4+ E. coli	0	1	0	1
Enteric rod, non-E. coli	0	0	1	1
No S. aureus, no KEE, no E. coli	10	11	10	31
Sample not collected/ Withdrew from Study	1	2	3	6

SOURCE: "Bleach vs. Bubbles" Study, data gathered by author, 2020

Table 6: POEM Difference from Office Intake to 4 Weeks Post Intervention.
Wilcoxon p= (0.1458)

	Bleach Baths & Bathroom Cleaning	Bathroom Cleaning Only	Control	Total
Number (n)	18	19	17	54
Mean	1.94	4	0.53	2.22
Std	6.51	6.45	3.47	5.78
Min	-10	-2	-5	-10
1st Qtr	-1	1	-1	-1
Median	0	2	0	1
3rd Qtr	2.75	4.5	2	3
Max	19	21	11	21

SOURCE: “Bleach vs. Bubbles” Study, data gathered by author, 2020

Table 7: 4 Week Post Intervention Survey

	Bleach Group & Cleaning Group	Control	Total/ p-values
History of Skin Infection in the Last 4 Weeks?	-	-	<i>Fisher p = (0.3541)</i>
No	36 (90%)	16 (80%)	52 (86.7%)
Yes	1 (2.5%)	1 (5%)	2 (3.3%)
No Data	3 (7.5%)	3 (15%)	6 (10%)
Topical Antibiotics in the Last 4 Weeks?	-	-	<i>Fisher p = (0.2361)</i>
No	37 (92.5%)	16 (80%)	53 (86.7%)
Yes	5 (12.5%)	1 (5%)	1 (1.7%)
No Data	3 (7.5%)	3 (15%)	6 (10%)
Systemic Antibiotics in Last 4 Weeks?	-	-	<i>Fisher p = (0.7105)</i>
No	32 (80%)	15 (75%)	47 (78.3%)
Yes	5 (12.5%)	3 (15%)	7 (11.7%)
No Data	3 (7.5%)	3 (15%)	6 (10%)
Systemic Steroids in the Last 4 Weeks?	-	-	<i>Fisher p = (0.4912)</i>
No	33 (82.5%)	14 (70%)	47 (78.3%)
Yes	4 (10%)	3 (15%)	7 (11.7%)
No Data	3 (7.5%)	3 (15%)	6 (10%)
Visit to Medical Provider in last 4 Weeks for Eczema Flair?	-	-	<i>Fisher p = (0.3289)</i>
No	35 (89.7%)	15 (75%)	50 (87.4%)
Yes	2 (5.1%)	2 (10%)	4 (6.8%)
No Data	2 (5.1%)	3 (15%)	5 (8.5%)

SOURCE: "Bleach vs. Bubbles" Study, data gathered by author, 2020

APPENDIX 1: LIMITED SYSTEMATIC REVIEW

Introduction

Dilute bleach (sodium hypochlorite, NaOCl) baths are commonly recommended in clinical practice guidelines for pediatric eczema, also known as atopic dermatitis (AD) management (Eichenfield, 2004, Weitz et al., 2006). Bleach baths are proposed to suppress epidermal *Staphylococcus Aureus* load, which subsequently improves atopic dermatitis severity (Guzik et al., 2015). Although the original randomized control trials (RCT) of bleach baths were promising, subsequent RCTs have shown conflicting results (Chopra et al., 2017). Additional evidence from a Cochrane review indicates that reducing the load of *Staphylococcus Aureus* in patients with atopic dermatitis does not provide clinical benefit in the absence of active infection (Bath-Hextall, 2010).

The “atopic triad” of disease includes asthma, atopic dermatitis, and allergies that are commonly inherited together and are a result of hypersensitivity to certain stimuli (Kapoor et al., 2008). The relationship between environmental interventions and disease severity are much better understood in conditions like asthma than for atopic dermatitis. Bleach baths are inexpensive, widely accessible, alternative antibiotic treatment that may not worsen antibiotic resistance. This systematic review will analyze the current literature for the efficacy of bleach baths for both symptom management and infection reduction for pediatric atopic dermatitis patients.

Methods

Scope of Review

This review is intended to create a descriptive analysis of currently existing evidence regarding efficacy of bleach baths for symptom management and infection reduction for pediatric atopic dermatitis patients.

Search Strategy

I searched PubMed and Cochrane Library databases for studies. The following search criteria were used in both searches: (Bleach baths OR sodium hypochlorite) AND (pediatric OR child OR children OR adolescent) AND (atopic dermatitis OR eczema).

The PubMed search yielded 30 publications, while the Cochrane search identified only 1 publication. I also performed hand searching and examined reference lists of expert opinion publications for any additional empirical studies. The last searches were performed on April 24, 2020.

Assessing articles for inclusion/exclusion

I first screened search results by title and abstract using eligibility established a priori (Table1). After exclusion of irrelevant studies based on title and abstract, full articles were screened for inclusion. Inclusion criteria specified studies involving patients aged 6 months to 18 years of age diagnosed with atopic dermatitis. Studies were included from any country, published online in English before January 1, 2020. Included study designs were randomized control trials, non-randomized trials, case control studies, cohort studies, retrospective and prospective studies, and cross-sectional studies. Excluded study types were noncomparative studies, reviews, case reports, case series, abstracts, conference presentations, expert opinion pieces, non-

empirical evidence, and editorials. The exposure of interest was use of bleach baths. Outcomes included skin infection rates, patient reported symptom changes (through tools like the patient-oriented eczema measure or POEM score, Appendix Item 1), de-escalation of atopic dermatitis therapy, or provider determined EASI score (eczema assessment severity index, Appendix Item 2).

Table 1: Inclusion and Exclusion Criteria

	Include	Exclude
Populations	Pediatric patients (6months-18 years) with diagnosed atopic dermatitis	Children less than 6 months of age or adults older than 18, those without diagnosis of atopic dermatitis
Intervention	Dilute bleach bath according to clinical practice guidelines (frequency and dilution levels) alone or in conjunction with topical corticosteroids or systemic immunotherapy	Dilute bleach baths outside of clinical practice guidelines (frequency and dilution level)
Comparisons	No bleach baths +/- topical corticosteroids or systemic immunotherapy	All other comparisons
Outcomes	Skin infection rates, POEM score, EASI score, de-escalation of current therapy	All other outcome
Study Designs	Randomized controlled trials, non-randomized trials, case control study, cohort study, retrospective and prospective study,	Noncomparative studies, reviews, case reports, case series, abstracts, conference presentations, editorials, and expert opinions
Setting	Any country setting	N/A
Language	English	All other languages

Assessing Quality of Eligible Studies

I assessed each publication for risk of bias using a modified version of the ROBINS-I tool (2016 version), which is a widely accepted tool for evaluating risk of bias in estimates of the comparative effectiveness (harm or benefit) of interventions from studies that did not use randomization to allocate units to comparison groups (Sterne,

2016). The risk of bias assessment was performed by one reviewer. Studies were not excluded based on quality issues, in order to avoid excluding relevant findings.

However, quality of studies was considered based upon risks verses benefits, level of study design, comparability between groups, reporting of outcomes, and transparency in methodology.

Data Extraction

I performed data extraction manually and I was the sole reviewer. Data points that were extracted included first author, year of publication, study design, comparison/control arm, type of intervention, number of patients enrolled in study, age, gender, level of blinding, baselines severity instruments and means, severity scale used for inclusion and whether thresholds were provided, inclusion and exclusion criteria, atopic dermatitis diagnostic criteria, medication use, bathing protocol, bleach concentration, duration and frequency of baths, bath-aftercare, non-adherence criteria, length of study, severity scores, *S. aureus* colonization, and frequency of adverse events. Extracted data were examined twice to ensure completeness. Principle summary measures included any barriers identified in publications' analysis of reporting barriers among survey and patient reported data.

Results

The search identified 28 publications. The publications underwent screening by title and abstract, and 16 were determined to be irrelevant for the purposes of this review. The remaining 12 were screened with full text review. Studies were excluded

based upon criteria outlined within Table 1. The final analysis included 12 publications. Figure 1 describes the article flow for inclusion and exclusion in this systematic review. Figure 2 details the critical appraisal and results from this literature review.

Figure 1: Study Inclusion and Exclusion PRISMA Flow Chart

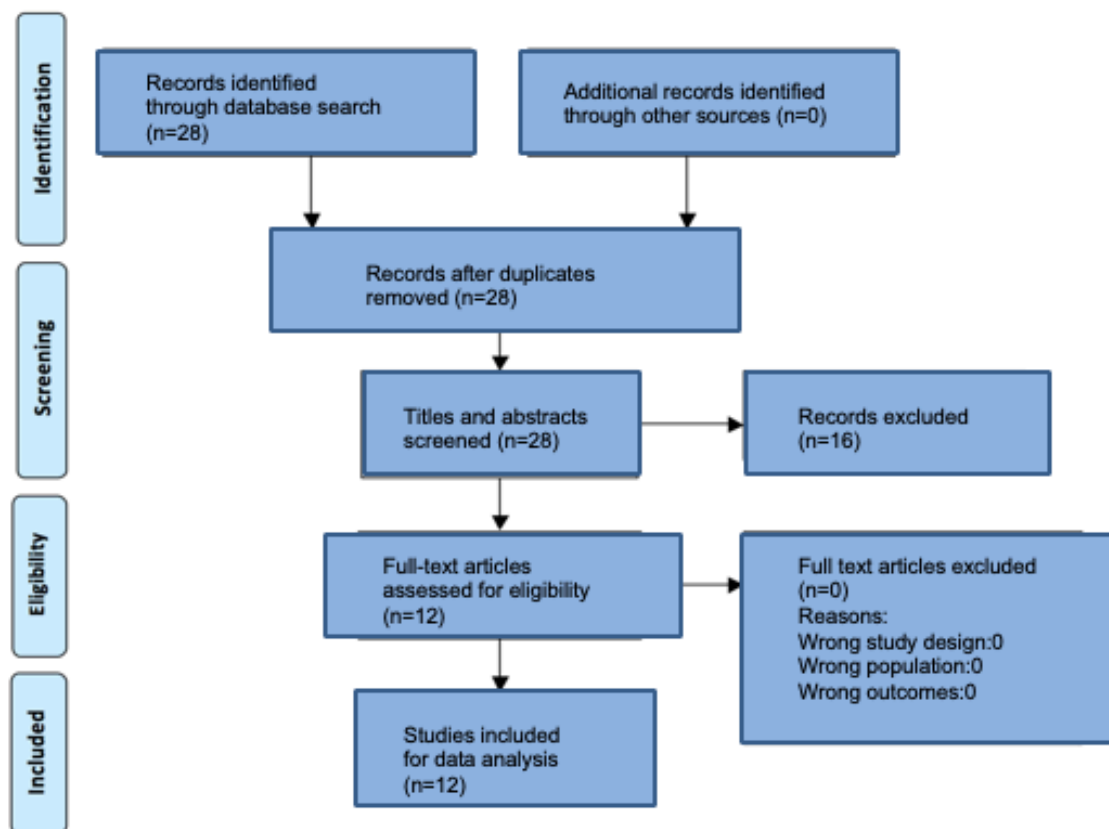


Figure 2: Critical Appraisal Table

Title	Author/Year	Design	Methods	Risk of Bias	Results	Notes
"Interventions to reduce <i>S. aureus</i> in the management of eczema"	Mc George et al. (2019)	Systematic Review	Cochrane review, assessed for improvement in QoL, adverse events, emergence of abx resistance.	Medium. Not detailed in review process or number of reviewers, definitions of QoL.	Inconclusive evidence on use of methods to reduce staph load with studies showing moderate ROB.	Addresses bleach baths but not primary intervention focus
"A Randomized Controlled trial of an Eczema Care Plan"	Rea et al. (2018)	Randomized Control Trial	211 caregivers gave pre and post intervention surveys for various eczema care plans.	Medium, no mention of how compliance was measured	Patients with more aggressive care plans (including bleach baths) reported improved eczema symptoms.	Bleach baths addressed but not primary intervention, also included wet wraps.
"Treatment of <i>S. aureus</i> colonization in AD decreases disease severity"	Huang et al. (2009)	Randomized Control Trial	Abx only arm vs bleach bath + abx or intranasal petrolatum ointment + plain water baths	Low, double blinded study though did not address confounders or measures of compliance.	Patients who chronically use bleach baths and intranasal petrolatum ointment reported decreased eczema severity.	Used EASI score, not POEM.
"Comparing the effect of bleach and water baths on skin barrier function in AD: a split-body RCT"	Shi et al. (2016)	Randomized Control Trial	Bleach bath arm vs water only baths twice per week	Medium, no compliance measures, no details on blinding.	No statistically significant difference in eczema severity between the two groups	Used EASI and POEM
"Efficacy of bleach baths to reduce <i>S. aureus</i> colonization in moderate to severe eczema: A randomized, placebo-controlled cross over trial"	Hon et al. (2016)	Cross over trial	40 patients with moderate to severe AD received twice weekly bleach or water baths for 4 consecutive weeks. Took blood, assessed QoL, and TEWL.	Low, does good job discussing confounders and triangulation of data.	No statistically significant difference in eczema severity between water and bleach group.	How do they "placebo" the smell of bleach? Used SCORAD
"Novel bleach cleanser shows clinical response in AD"	Ryan et al. (2013)	Retrospective and prospective non-randomized feasibility study	Kids had to be staph positive at time of recruitment, open label feasibility study. Use wash 3x per week for 12 weeks.	High, non-randomized, funded by company developing wash.	Patients who used bleach product reported improved eczema severity.	Used IGA scale
"Use of bleach baths for	Barnes et al. (2013)	Case series	Use of bleach baths vs water	Medium, does not address	Bleach baths are effective in	Only looked at infection rates,

treatment of infected AD"			baths twice weekly for four weeks.	confounding or compliance.	reduction of skin infection rates in AD.	not necessarily eczema severity.
"Bleach body wash in the management of <i>S. aureus</i> colonized moderate to severe AD in infants, children, and adolescents"	Bhattacharya et al. (2019)	6-week open label prospective study	50 participants with moderate to severe AD with <i>S. aureus</i> skin colonization documented by culture, used wash once daily for 6 weeks.	High, funded by wash company, does not discuss confounders or compliance.	Daily use of bleach wash was shown to have improved outcomes for eczema severity.	Ironically only showed limited reduction in <i>S. aureus</i> load.
"Efficacy and safety of bleach baths in patients with moderate to severe AD in Malaysia"	Wong et al. (2013)	Retrospective case series.	Survey administered to patients who had been recommended bleach baths	Medium, risk of recall bias given retrospective study design.	Improved severity of AD in those who reported high compliance with recommended bleach baths.	Not detailed on severity scoring
"Comparison of bleach, acetic acid, and other topical anti-infective treatments in pediatric AD: a retrospective cohort study on antibiotic exposure"	Asch et al. (2019)	Retrospective cohort study	Chart review from patients 2000-2015, primary outcome use of antibiotics	High, bias within charting, knowing compliance rate of recommended treatments	Bleach baths were not associated with less antibiotic use.	Antibiotic use was primary outcome
"Cutaneous microbiome effects of fluticasone propionate cream and adjunctive cream and adjunctive bleach baths in childhood AD"	Gonzalez et al. (2016)	Randomized, placebo controlled, single blinded	21 children with AD and 14 healthy children, examined lesional and non-lesional skin at baseline and after 4-week treatment with TCS alone or TCS plus bleach baths. PCR analyzed.	Medium, short follow up time. Primary outcome was PCR sequencing not eczema severity.	Treatment with a TCS cream suffices to normalize the cutaneous microbiota on lesional AD; after treatment, bacterial communities on lesional skin resemble nonlesional skin but remain distinct from control.	Not detailed on tools of measurement.

APPENDIX 2: METHODS

The POEM Score

Outcome methodology for atopic dermatitis has been a relatively neglected and unstandardized area of research. Currently, there is bias toward allegedly more objective measurements, deemed to be more reliable, from the physician standpoint rather than patient-centered assessments (Charmin et al., 2013). This approach has

been problematic as it neglects symptomatic improvement and overall patient experience with atopic dermatitis. The Patient-Oriented Eczema Measure (POEM) is a validated, patient derived assessment measure for monitoring atopic dermatitis severity (See Appendix Item 1) (Charmin et.al 2004). The POEM score was developed after more than 56 objective scoring systems recording different combinations of physical signs were identified in published randomized controlled trials between 1994 and 2001, with several measures having no data on reliability or validity (Charmin et al 2004). Interpretation of objective measurements obtained by clinicians is difficult for understanding implications on patient morbidity. Recently, health care experts have placed more recognition of the importance of measuring disease severity and daily lived challenges from the patient perspective (Clayton et al.,2007). Patient based outcome measures that address symptoms, including quality of life, functional ability, pain, and satisfaction of care have become increasingly popular for use as primary or secondary outcomes in clinical trials, which provide for a more holistic and relevant evaluation for health care interventions (Clayton et al.,2007).

The POEM score was developed out of a study of qualitative semi-structured patient interviews to identify which symptoms were most important to 435 patients in seen at the outpatient Department of Dermatology at the Queen's Medical Centre in Nottingham, England, as well as 5 surrounding local general practices (Charmin et al.,2004). Patients were asked open-ended questions about the aspects of their disease that affected them, including "What bothers you about your eczema (AD)?" and "What troubles you most about your eczema?" (Charmin et al., 2004). Interviews were audiotaped and transcribed with major themes of symptoms recorded. For young

children, information was obtained from both the child and parents, depending on the child's age and understanding (Charmin et al., 2013). Using answers obtained from these qualitative interviews, the morbidity caused by each symptom was strongly related to how frequently each symptom was experienced.

While investigators developed the POEM Score, nearly 200 patients completed a questionnaire at the interview, however questions regarding skin tightness and redness were completed in fewer than 75% of respondents because of difficulties in understanding or assessing these symptoms (Charmin et al., 2013). Redness was also difficult to assess for patients with Afro-Caribbean or Asian skin types (Charmin et al., 2004). Due to these difficulties, redness and tightness were excluded from the final outcome measure. The assessment of "soreness" was also difficult to capture, with parents of 35 children (all less than 4 years old) felt unable to assess this symptom on their child's behalf (Charmin et al., 2004). Retention of soreness as a final outcome measure in the POEM Score would have necessitated a separate scoring system excluding soreness for children younger than 4 years. Given this challenge, this symptom was also excluded (Charmin et al., 2013). The remaining 7 symptoms including itch, sleep disturbance, bleeding, oozing, cracking, and flaking were combined into a simple POEM that allowed patients to record the frequency of experiencing these symptoms with a maximum score of 28 (Charmin et al., 2004).

Content validity of the POEM score was shown by the fact that measured domains were directly derived from patient interviews with no further symptoms identified among an additional 200 patients that were questioned (Charmin et al. 2013). Construct validity measures agreement with other related variables, in this case patient

assessments of disease-related quality of life. Correlation showed reasonably good agreement between new measures and the Dermatology Quality of Life Index and Children's Dermatology Life Quality Index (Clayton et al., 2007). Ideally, determination of criterion validity involves correlation against a "gold-standard measure".

Unfortunately, there was no accepted gold-standard patient-based measure of atopic dermatitis severity. Thus, criterion validity was measured against patient global assessments of disease severity, which is a 5-point scale, and overall bother related to atopic dermatitis, which is a 10-point scale (Clayton et al., 2004). In comparison to these two scales, there was a high correlation with both assessments ($n=20$; $r=0.81$, and $r=0.84$ respectively, $P<0.001$) (Clayton et al., 2004).

The POEM Score is a simple, valid, easily interpreted, and reproducible tool for assessing the patient experience with atopic dermatitis symptoms. This measure captures the fluctuation and chronic nature of atopic dermatitis. The POEM Score is based on patients' views of what constitutes disease severity and quality of life rather than what physicians and health care providers presume to be of importance to patients. This tool can be completed by most patients in 1 to 2 minutes and has proven to be a useful tool in routine clinical practice to give a better picture of symptom management at home (Clayton et al., 2004). While further studies are needed to confirm its usefulness in the clinical trial setting it is still a practical tool to provide standardization of patient-based outcomes.

Bleach vs Bubbles Official Protocol:

1. Patient Enrollment [Target = 60 patients with moderate to severe Eczema]
 - Obtain consent/assent of patient and parent
 - Assign study ID number
 - Record telephone number and address for scheduling home visit
 - Record insurer, age, race/ethnicity, history of skin infections, history of atopic diseases (doctor diagnosed asthma, hay fever, food allergies), current antibiotic use (topical or oral)
 - Obtain POEM score and eczema treatment level
 - Randomize 2/3 of patients to intervention arm (bathroom cleaning) and 1/3 to control arm (no cleaning) using RANDBETWEEN() function in Microsoft Excel
 - [1,2] = intervention arm, [3] = control arm
2. Schedule Home Visit
- 3a. Home Visit for Intervention Arm
 - Obtain baseline photographs of bathrooms taking care to document the bathtub and any damage prior to cleansing
 - Obtain bacterial culture from floor and sides of bathtub
 - Clean bathrooms using provided products
 - Obtain follow up photographs of bathroom after cleaning
 - Perform qualitative interview
 - Call blinded POEM score assessor (Dr. Burkhardt, Morrell, Evans, or McShane) to obtain baseline POEM score and link to study ID number
 - Randomize ½ of patients to bleach bath teaching arm and ½ to no further intervention using RANDBETWEEN() function in Microsoft Excel
 - [1] = provide bleach bath teaching, [2] = do not provide bleach bath teaching
 - Complete qualitative reflection
- 3b. Home Visit for Control Arm
 - Obtain photographs of bathroom used by patient taking care to document the bathtub
 - Obtain bacterial culture from the floor and sides of bathtub
 - Call blinded POEM score assessor (Dr. Burkhardt, Morrell, Evans, or McShane) to obtain POEM score and link to study ID number
4. One Week Follow-Up
 - Blinded POEM score assessor (Dr. Burkhardt, Morrell, Evans, or McShane) calls to obtain POEM score and link to study ID number
 - The same person reports culture results to family and instructions on how to sanitize bathroom if a pathogen is found (*S. Aureus*).
5. Four Week Follow-Up
 - Blinded POEM score assessor (Dr. Burkhardt, Morrell, Evans, or McShane) calls to obtain POEM score and link to study ID number
 - Also document current level of eczema therapy, antibiotic use in last 4 weeks (topical or oral), visits to medical providers or hospitals for atopy flares in last 4 weeks

Cleaning Steps for Home Investigator:

BEFORE ANYTHING:

- **TAKE BEFORE PHOTO OF BATHROOM w/DISPOSABLE CAMERA******
- Put a grocery bag in the bucket to use as your trash bag

1. TUB/SHOWER

- sponge with disinfectant solution over tub/tile walls (basically all over)
- fill blue bowl with H₂O and rinse off
- (other bowl) fill with ¼ baking soda + H₂O and use sponge w/this over same areas as disinfectant and rinse
 - (KEEP the baking soda/water mixture for later—just set aside for now)

2. DRAIN

- Baking soda + apple cider vinegar (ACV) and let sit 15 minutes

****while you're waiting on the drain to "soak" is perfect time to finish up the rest of the bathroom**** (I usually would set a timer on my watch for the drain since it's easy to lose track of time)

3. TOILET

- Paper towel + disinfectant
 - Essentially on all "external" parts of the toilet
 - Good to use paper towels for this as they are easy to throw away
- Spray disinfectant into toilet bowl and scrub with toilet brush
- Baking soda + water mixture and basically just "dump" it throughout the toilet bowl and scrub with toilet brush
- FLUSH
 - (toilet is now done! I like putting the brush over the toilet bowl and setting the toilet seat on top of the handle to let it dry before packing up)

4. COUNTERS/CABINETS

- Paper towel + counter solution

5. GLASS/MIRRORS

- CLOTH rag + ACV mirror solution
 - It does NOT take much!
 - The cloth rags are key
 - 1. (reduce smudging vs. using something like paper towel)
- *if there are any chrome-type material knobs, handles, etc. throughout the bathroom, I'll try to use the cloth rag and mirror solution to buff them

6. FLOORS

- Shake out any rugs, do quick sweep

- Spray floor solution everywhere, do easy scrub with Swiffer rag on Swiffer tool

7. *WRAPPING UP BATHROOM PORTION*

- Run some water down the drain and get rid of any baking soda residue
- TAKE AFTER CLEANING PICTURE

FINAL STEPS

- Show the bathroom to the family/whoever is at the house that you spoke with upon arriving (typically mom and patient)
 - Run through the general steps of the cleaning process/what you used to explain to them what you did
 1. Hand them their copy of the cleaning supplies, recipes, and information on how to clean, leave it with them as a resource.
- Time for FINAL INTERVIEW
 - Run through the questions at the BOTTOM of the “Step 2B Home Visit Qualitative Analysis” document with the parents
 1. (this is the same document where you will fill in your observations throughout the visit—i.e. status of the home, neighborhood, etc.)

- **CALL BLINDED INVESTIGATOR FOR POEM SCORE**

Item 1: POEM Score

Step 2-b: Home Visit POEM (Blinded Telephone Call)

Study ID #__

Assessor: _____

Bleach versus Bubbles

POEM score: _____

1. Over the last week, on how many days has your child's skin been itchy because of their eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day
2. Over the last week, on how many nights has your child's sleep been disturbed because of their eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day
3. Over the last week, on how many days has your child's skin been bleeding because of their eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day
4. Over the last week, on how many days has your child's skin been weeping or oozing clear fluid because of their eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day
5. Over the last week, on how many days has your child's skin been cracked because of their eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day
6. Over the last week, on how many days has your child's skin been flaking off because of their eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day
7. Over the last week, on how many days has your child's skin felt dry or rough because of their eczema?
No days | 1-2 days | 3-4 days | 5-6 days | Every day

Item 2: EASI Scoring Guide

How to Use EASI

The EASI scoring system uses a **defined process** to grade the **severity of the signs** of eczema and the **extent affected**:

1. Select a body region

Four body regions are considered separately:

- Head and neck
- Trunk (including the genital area)
- Upper extremities
- Lower Extremities (including the buttocks)

2. Assess the extent of eczema in that body region

Each body region has potentially 100% involvement. Using the table below, give each respective body region a **score of between 0 and 6** based on the percentage involvement. Precise measurements are not required.

% involvement	0	1-9%	10 - 29%	30 - 49%	50 - 69%	70 - 89%	90 - 100%
Region score	0	1	2	3	4	5	6

To aid in your body region grading you can use the **diagrams** in **Appendix 1**.

3. Assess the severity of each of the four signs in that body region:

1. Erythema
2. Edema/papulation
3. Excoriation
4. Lichenification

Further explanations of these terms can be found in FAQ's (Appendix 4)

Grade the severity of each sign on a scale of 0 to 3:

0	None
1	Mild
2	Moderate
3	Severe

- ✓ Take an average of the severity across the involved region.
- ✓ Half points (1.5 and 2.5) may be used. 0.5 is not permitted – if a sign is present it should be at least mild (1)
- ✓ Palpation may be useful in assessing edema/papulation as well as lichenification

To aid your severity grading, a **photographic atlas** of suggested categories is available in **Appendix 2**

Remember: Include only inflamed areas in your assessment; do not include xerosis (dryness), ichthyosis, keratosis pilaris, urticaria, infection (unless there is underlying eczema), or post inflammatory pigmentation changes.

How to record your scores

The assessed parameters are inserted into a table (example shown below for age ≥ 8 years). The final EASI score ranges from 0-72.

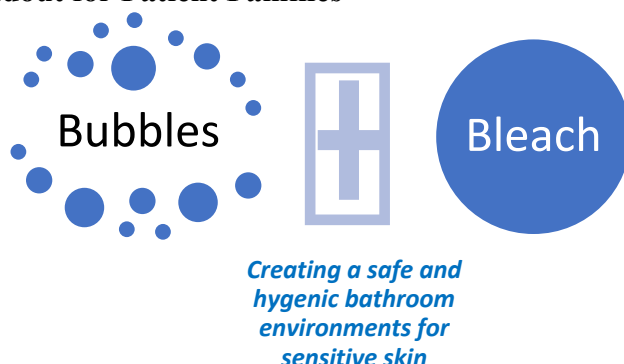
Body region	Erythema	Edema/papulation	Excoriation	Lichenification	Area score	Multiplier	Score
Head/neck	(+)	+	+	+	x	x 0.1	
Trunk	(+)	+	+	+	x	x 0.3	
Upper extremities	(+)	+	+	+	x	x 0.2	
Lower extremities	(+)	+	+	+	x	x 0.4	
The final EASI score is the sum of the 4 region scores							(0-72)

Two forms of the EASI scoring system are available depending on the age of the patients. The multipliers for the region score are different in the under 8's version to reflect the relative proportion of body regions in young children:

- Patients 8 years or above
- Patients under 8 years of age.

The forms can be found in appendix 3.1 and 3.2 and also as word documents on the HOME website (www.homeforeczema.org)

Item 3: Cleaning Handout for Patient Families



Bathroom Cleaning Recipes

Counters, Floors, and Walls	Mix 7 drops of dish soap in a standard size (24 oz.) spray bottle and fill with water.
Tubs, Tiles, Showers, Toilets	Mix baking soda with warm water.
Floors	Add a half cup white vinegar to a half gallon water. No need to rinse. Cleans linoleum and tile.
Glass	Mix a half cup of white vinegar with a half cup water.
Drains	Pour a half cup of baking soda down the drain, then a half cup white vinegar. Wait 15 minutes, then pour hot water down the drain.
Areas of Mold growth on hard surfaces	Mix 1 cup (8 ounces) of bleach with 1 gallon of water. Scrub with a stiff brush and rinse with clean water. Allow to air dry.
Disinfecting areas: cleaning areas where someone has an infection (we will use this method for the bathtubs and showers)	Mix 1 quart of water, add 1 tablespoon bleach. Wipe down with a clean cloth or sponge. Allow to air dry.

Bathroom Cleaning Resources:

The Centers for Disease Control and Prevention resources:

- Household Cleaning and Sanitizing:
<https://www.cdc.gov/healthywater/emergency/cleaning-sanitizing/household-cleaning-sanitizing.html>
- Caring for Yourself While Caring for Others. Module 3: Tips for Reducing Risks from Environmental Exposures When Providing Homecare:
<https://www.cdc.gov/niosh/docs/2015-102/module3.html>

Oregon Homecare Commission.

- Safety Manual for Homecare Workers:
<http://apps.state.or.us/Forms/Served/de9062.pdf>

Item 4: Qualitative Guide for Home Investigator

Step 2b: Home Visit Qualitative Assessment (to be typed and printed)

Study ID# _____

Bleach versus Bubbles

Domain 1: Environment

1. Description of neighborhood, general appearance of home, and presence of pets, pests, fragrance, dust, evidence of smoking, or water damage [triggers].
2. Description of the bathrooms (musty smell or evidence of mold?) (**OBTAIN PRE- AND POST-CLEANING PHOTOGRAPHS**).*
3. Description of hospitality and interactions with host family [personal contact quality and Nickel and Dimed].
4. Description of bonding and support from co-investigators [Nickel and Dimed].

Domain 2: Work difficulty

1. Description of activities performed [Nickel and Dimed].
2. Description of any physical, mental, or emotional difficulties related to cleaning [Nickel and Dimed].
3. Suggestions for improving work experience and/or making the work more efficient.

Domain 3: Assessment of service satisfaction, self-efficacy, and planning

1. Does the family expect the bathroom cleaning and education to be helpful for their child's eczema [accuracy and quality]?
2. Did the family find the bathroom cleaning met or exceeded their expectations [condition and quality]? Does the family feel the bathroom is in better condition after the cleaning [condition]?
3. Was the family satisfied with the scheduling and timeliness of the cleaning [timeliness]?
4. Does the family have recommendations to make the intervention more useful for eczema care?
5. Did the family understand the cleaning sheet and plan to use any of the cleaning techniques we used in the future [information quality]?
6. If provided, did it seem that the family understood and planned to follow the bleach bath instructions [information quality]?

References and Explanation of Themes:

Ehrenreich B. Nickel and Dimed: On (Not) Getting By in America. Henry Holt and Company 2001.

- *Used to obtain work difficulty themes (<https://www.litcharts.com/lit/nickel-and-dimed/themes>)*

Soh KL, Chin SH, and Wong WP. A theoretical model to investigate customer loyalty on logistics service providers for sustainable business performance. Int. J. Business Performance and Supply Chain Modelling. 2015. 7(3):212-232.

- *Utilized for service satisfaction themes*

National Cancer Institute. Theory at a Glance: A Guide for Health Promotion Practice. 2005. NIH Publication No. 05-3896.

- *Utilized elements of Precaution Adoption Process Model and Social Cognitive Theory for planning questions*

Eichenfield et al. Current guidelines for the evaluation and management of atopic dermatitis: A comparison of the Joint Task Force Practice Parameter and American Academy of Dermatology guidelines. J Allergy Clin Immunol 2017;139:S49-57.

- *Utilized for environmental triggers question*

|

Item 5: Patient Information and Instructions on Bleach Baths

How to Make Dilute Bleach Baths

Baths with a small amount of bleach in them may be helpful for your child's atopic dermatitis by helping to get rid of germs that cause infections. You should be careful when giving bleach baths. Bleach that is not watered down (diluted) is a dangerous household poison.

- DO NOT use undiluted bleach directly on the skin.
- DO NOT let dilute bleach water get in your child's eyes or in your eyes.
- DO NOT swallow dilute bleach water.
- Drain any unused bleach or bleach water right after use.
- Keep your bleach bottle out of reach of children.
- Bleach can make your bathtub slippery, so be careful to keep your child from falling.

Give your child a dilute bleach bath 2 times a week:

1. **Use unscented household liquid bleach (like Clorox).** Look at the bottle to check the concentration of bleach. On the bottle, "bleach" might be called "sodium hypochlorite." These mean the same thing. The concentration should be around 6 to 8.75%.
2. **Measure the amount of bleach before adding it to the bathwater.** Use a measuring cup or measuring spoon to add the bleach to the bath. For a full bathtub of water, use a half cup of bleach. For a half-full bathtub of water add a quarter cup of bleach. For a baby or toddler bathtub, add one teaspoon of bleach per gallon of water.
3. **While the tub is filling, pour the bleach into the water.** DO NOT apply bleach directly to your child's eczema
4. **Wait until the bath is fully drawn and bleach is poured before your child enters the bathtub.**
5. **Soak for 10 minutes.**
6. After soaking, **rinse your child's skin** very well with fresh, clean, lukewarm water.
7. **Pat your child's skin dry** after the bath. Use white towels to avoid bleach stains.
8. **Apply your child's eczema medications** immediately after the bath. Then **moisturize** your child's skin.

This information sheet on bleach baths was made using information from websites created by the American Academy of Dermatology and the American Academy of Allergy Asthma & Immunology. You can also visit these websites to learn more about bleach baths.

1. Eczema and bleath baths: Follow dermatologists' instructions to keep children safe (January 8, 2014): <https://www.aad.org/media/news-releases/eczema-and-bleach-baths>
2. Atopic Dermatitis: Bleach Bath Therapy: <https://www.aad.org/public/diseases/eczema/atopic-dermatitis#bleach-bath>

3. Bleach Bath Recipe for Skin Conditions: <https://www.aaaai.org/conditions-and-treatments/library/allergy-library/bleach-bath-recipe-for-skin-conditions>

Item 6: Step 1 In-Office Encounter**Step 1: In-office Encounter**

Study ID# _____

Bleach versus Bubbles

Treatment category: _____ Class 1 Topical Steroid | _____ Systemic immune modulator

EASI score: _____

POEM score: _____

1. Over the last week, on how many days has your child's skin been itchy because of their eczema?
_____ No days | _____ 1-2 days | _____ 3-4 days | _____ 5-6 days | _____ Every day
2. Over the last week, on how many nights has your child's sleep been disturbed because of their eczema?
_____ No days | _____ 1-2 days | _____ 3-4 days | _____ 5-6 days | _____ Every day
3. Over the last week, on how many days has your child's skin been bleeding because of their eczema?
_____ No days | _____ 1-2 days | _____ 3-4 days | _____ 5-6 days | _____ Every day
4. Over the last week, on how many days has your child's skin been weeping or oozing clear fluid because of their eczema?
_____ No days | _____ 1-2 days | _____ 3-4 days | _____ 5-6 days | _____ Every day
5. Over the last week, on how many days has your child's skin been cracked because of their eczema?
_____ No days | _____ 1-2 days | _____ 3-4 days | _____ 5-6 days | _____ Every day
6. Over the last week, on how many days has your child's skin been flaking off because of their eczema?
_____ No days | _____ 1-2 days | _____ 3-4 days | _____ 5-6 days | _____ Every day
7. Over the last week, on how many days has your child's skin felt dry or rough because of their eczema?
_____ No days | _____ 1-2 days | _____ 3-4 days | _____ 5-6 days | _____ Every day

Age: _____ months/years

Ethnicity: Latino/Hispanic

Race:

White	Black or African American	American Indian or Alaskan	Asian	Native Hawaiian or Pacific Islander	Other: _____	Mixed/Two or more races
-------	---------------------------	----------------------------	-------	-------------------------------------	--------------	-------------------------

Insurer: _____

Other atopic disease?

Doctor diagnosed asthma	Hay fever/seasonal allergies	Doctor diagnosed food allergies	None
-------------------------	------------------------------	---------------------------------	------

History of skin infections requiring antibiotics? Yes No

Current topical antibiotic use? Yes No

Current systemic antibiotic use? Yes No
Study ID# _____

Home Visit scheduling information:

Name of Patient: _____

Name of Parent(s) who will be present during home visit: _____

Telephone number: _____

Address: _____

Date and Time of Home Visit: _____

Investigators Attending Home Visit: _____